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Original Research Article

Mispa count X; The first indigenous indian hematology 3-part analyzer

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ABSTRACT

Background: Impedance technology was a revolution in the history of Hematology. Mispa Count X is the first indigenous 3-part hematology analyzer in India, which works on the principle of impedance technology.
Aim: Performance evaluation of Mispa Count X.
Design & Methods: The analyzer produces the measurement results of 18 parameters with throughput of 60 samples per hour. Mispa Count X was compared with benchmark analyzers Coulter DxH 800 and Sysmex XN 1000 to validate its performance.
Result & Discussion: Mispa Count X exhibited a wide linearity range for WBC, RBC, platelet and hemoglobin. The carry over for WBC, RBC, PLT and Hb was estimated and found to be well within the acceptable limits. The r^2 values (> 0.90) and bias estimation of Mispa Count X on comparing with Coulter DxH 800 and Sysmex XN 1000 were acceptable, except for mid cell counts and for MPV. Mispa Count X exhibited good precision with an acceptable CV% (< 10%). The primary parameters of the stored samples were stable at room temperature for 24 hours.
Conclusion: So we conclude our study by proving that the Mispa Count X would be an affordable-reliable alternative for Indian healthcare sector instead of expensive imported hematology analyzers.

1. Introduction

The invention of impedance technology and its application in cell counting by Charles Wallace Coulter heralded the beginning of new era in hematology.[1] Sysmex Corporation which used conductance technology in hematology counters shifted to impedance technology in their analyzers.[2] Today, automation in Hematology is accepted worldwide, which improves accuracy and speed of cell counting, reduces the manual workload and enables the blood cell counting of other body fluids than blood.[3] Adapting to this advanced technology helps to omit errors caused due to the limitations in the traditional microscopic counting; The most common errors in the traditional technique can be classified into three vide: the statistical error (due to lower number of cells counted), distributional error (due to unequal distribution of cells in smear) and the error due to mistakes in subjective interpretation of the technicians.[4,5]

Blood cell count is one of the mostly prescribed blood tests, as these directly indicate the overall physiological health status of an individual. Complete blood count and differential blood count are widely used in diagnosis and

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prognosis of diseases. So the authentication of results produced by any hematology analyzer must be proved.[6,7] A few clinical cases are listed below which support the relation of blood cell counting with disease and treatment progress Dengue fever is characterized by low leukocyte count in the initial stage and platelet count lowers as the disease progresses.[8] The mortality rate in case of peritoneal dialysis patients can be envisaged by testing red cell distribution width.[9] The health progress in allogeneic peripheral blood stem cell transplantation can be monitored using platelet count.[10] Quantification of lamellar bodies in amniotic fluids is a useful method to determine fetal lung maturity.[11]

Mispa count X, being the first indigenous 3-part hematology analyzer in India can reduce the import of expensive hemtology analyzers to a great extent. With this domestic invention that matches international quality, it is now affordable for common rural population. All evaluation protocols used for verification of Mispa Count X viz., linearity, carry over, precision and comparability are in reference to the CLSI standards and ICSH guidelines.

2. Materials and Methods

2.1. Analyzer

Mispa Count X is a tabletop, compact 3-part analyzer with 275 mm width, 436 mm height and 461 mm length. The analyzer has a 10.4" SVGA resistive touch Screen Display having a resolution of 800x600 with 24-bit colour depth. The equipment works efficiently at an ambient temperature of 15 - 35°C and at a relative humidity of 80% at 32°C. The analyzer can with stand temperature up to 50°C and altitude change up to 3000m without affecting the result.

Mispa Count X is a quantitative and automated 3-part haematology analyzer designed for In vitro Diagnostic use in clinical laboratory. The system is having a throughput of 60 samples /hour. Mispa Count X provides 18 clinical parameters & 3 Histograms (WBC, RBC & PLT), including a 3-part WBC differential. Analyzer has automatic flagging of results that are out of normal range and has a storage capacity of 35000 sample results, including parameter, histogram, and patient information. It has a thermal printer and is also provided with an option of connecting to an external printer.

The verification study of Mispa Count X, a 3-part Hematology analyzer designed and manufactured by Agappe Diagnostics Ltd was performed against Beckman coulter DxH 800 and Sysmex XN1000.

2.1.1. Specimens

The study procedures including blood collection technique, sample tubes, sample number etc., are performed as per the respective CLSI guidelines. Peripheral venous blood was collected in K2-EDTA anti-coagulated vacutainers from 180 patients.[12] The specimens were kept at room temperature and tested within 6 hours of sample collection.[13]

2.2. Data analysis

The statistical analyses were conducted by using Microsoft Excel (2013).

2.3. Linearity

The linearity test was done following CLSI guideline EP06-A. The linearity of leukocyte count, erythrocyte count, platelet count, hematocrit and hemoglobin concentration were evaluated using the linearity kits of R&D Biotechnie (CBC line 139). Each level of linearity control is run 4 consecutive times and the percentage deviation from the expected measurement is calculated.[14]

2.4. Carry Over

The carry over study evaluate whether the analyzer shows any effect of the high count/ blank measurement on low level count measurement. The carry-over of leukocyte count, erythrocyte count, platelet count and hemoglobin measurement were assessed following CLSI guideline H26-A2. To perform the study three consecutive run of high sample without any interruption were followed by the three consecutive low sample run. The same procedure was repeated with 3 blank run followed by 3 low control run to study the effect of blank run on expressing low count measurement.[15,16] The carry-over is calculated by using the following equation.

$$Percent\ carry\ over = \frac{(Low\ target\ value\ 1 - low\ target\ value\ 3)}{(High\ target\ value\ 3 - Low\ target\ value\ 3)} \times 100$$

2.5. Imprecision

Both long term and short term imprecision were performed following CLSI guideline EP05-A2. The repeatability was tested by running 5 different blood samples of normal measurable range, 31 times each. The coefficient of variation (CV %) was calculated. The reproducibility was established by running 3 levels of whole blood controls (normal, low and high) (Lot: 31030557) twice a day with 4 to 6 hours gap for 20 days. The CV% was calculated and assessed the within laboratory precision.[17]

2.6. Comparability (Correlation)

The comparison of Mispa Count X with Coulter DxH 800 and Sysmex XN 1000 were performed by testing 180 patient samples. The correlation coefficient was calculated for each parameter. The study protocol follows CLSI guideline EP09-A2.[18]

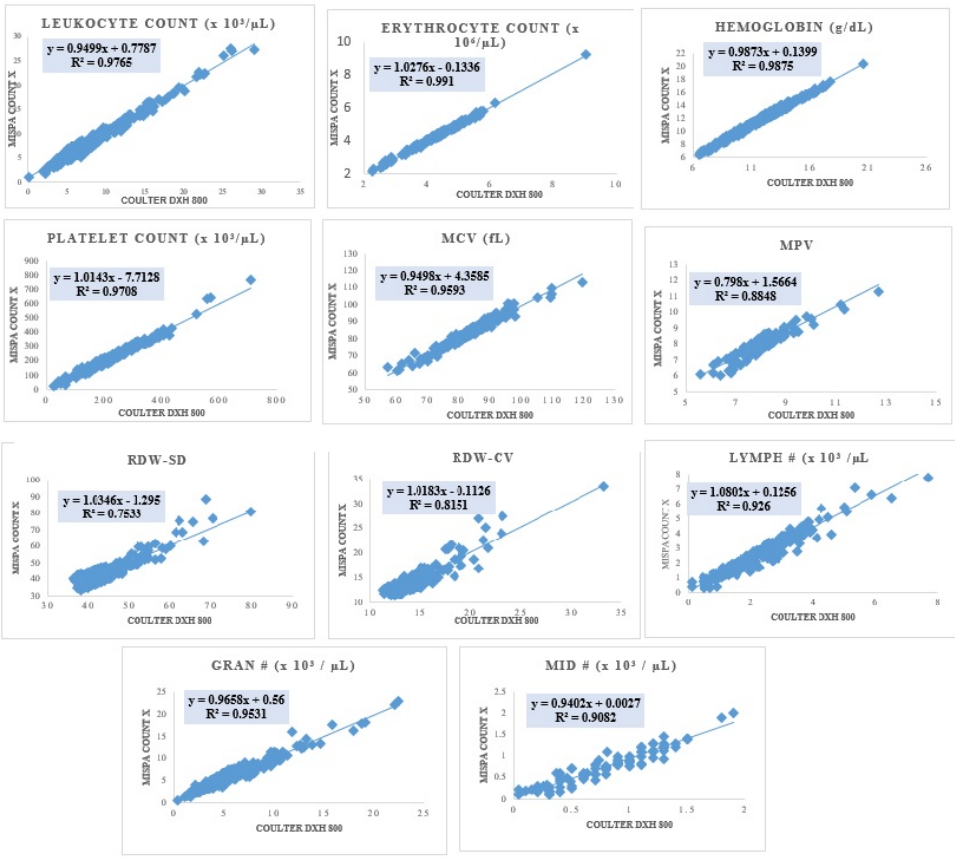

Fig. 1: Comparison of hematology parameters of Mispa Count X (Agappe Diagnositcs) with Coulter DxH 800 (Beckman Coulter). Abbreviations: MCV, mean corpuscular volume; MPV, mean platelet volume; RDW, red cell distribution width; Lym #, lymphocyte count; Mid #, mid cell count; Gran #, granulocyte count.

Table 1: Linearity. a) Full range linearity controls, b) Low level linearity controls of R&D Biotechnie Linearity kit (L# CBC-Line 130)

	WBC			RBC			Hb			PLT		
Levels of Control*	**Expected value**	**Obtained value**	**% Deviation**	**Expected value**	**Obtained value**	**% Deviation**	**Expected value**	**Obtained value**	**% Deviation**	**Expected value**	**Obtained value**	**% Deviation**
a) Full range linearity												
1	8.65	8.65	0	1.09	1.15	-5.41	3.43	3.425	-0.15	23.3	24	-2.89
2	17.3	16.45	4.91	2.17	2.28	-4.72	6.86	6.9	0.58	233.25	233.25	0
3	38.9	36.83	5.38	2.9	2.96	-1.96	9.15	9.225	0.81	466.5	464	0.535
4	73.5	77.6	-5.54	4.35	4.35	0	13.73	13.725	-0.04	1282.9	1224.3	4.57
5	90.8	95.12	-4.73	6.88	6.59	4.19	21.73	20.4	-6.52	1516.1	1423.8	6.09
6	121.1	123.7	-2.13	7.24	6.91	4.67	22.88	21.35	-7.17	2332.5	2241.5	3.9
b) low range linearity												
1	0.415	0.425	-2.41	0.212	0.225	-6.07	0.6	0	0	8.29	6.34	-23.5
2	0.83	0.875	-5.42	0.424	0.44	-3.71	1.2	1.175	-2.13	16.6	17.2	-3.8
3	1.66	1.675	-0.904	0.849	0.878	-3.42	2.4	2.4	0	33.2	35	-5.58
4	4.15	4.225	-1.8	2.12	2.19	-3.005	5.99	6.15	2.60	82.9	87	-4.98
5	5.81	5.925	-1.98	2.97	3.005	-1.18	8.38	8.5	1.41	116	120	-3.5
6	8.3	8.3	0	4.24	4.24	0	11.98	11.975	-0.04	165.8	165.8	0

*Each levels of controls tested consecutively from 1 – 6

Table 2: Carry over. a) On low samples by high value sample run. b) On low samples by blank run

		WBC	RBC	Hb	PLT
a)	H1	16.5	5.91	11.6	501
	H2	16.2	5.84	11.5	541
	H3	16.5	5.81	11.5	489
	L1	1.4	3.24	10.8	163
	L2	1.5	3.32	10.9	181
	L3	1.4	3.28	10.8	165
	Carry Over (%)	**0 %**	**-1.52%**	**0%**	**-0.595%**
b)	B1	0	0	0	0
	B2	0	0	0	0
	B3	0	0	0	0
	L1	1.4	3.28	10.9	164
	L2	1.4	3.4	11	158
	L3	1.4	3.18	10.9	162
	Carry Over (%)	**0%**	**-3.14%**	**0%**	**-1.23%**
	Manufacturer Specification	<1.5%	<1.5%	<1.5%	<2.5%

Table 3: Imprecision

Parameters	Value	Unit	Range CV % Specification	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
WBC	Mean	103/μL	> 6.0	6.73	5.25	5.63	6.14	6.17
	CV%	%	< 4.0%	3.35	3.33	3.44	2.55	1.75
RBC	Mean	106/μL	> 4.0	5.58	4.95	4.65	4.09	4.31
	CV%	%	< 4.0%	1.77	1.52	1.5	2.06	1.74
HGB	Mean	g/dL	> 12.0	15.65	14.65	13.04	11.71	13.38
	CV%	%	< 2.5%	1.7	1.24	2.26	1.72	1.24
HCT	Mean	%	> 35.0	46.25	41.65	40.67	32.94	40.99
	CV%	%	< 2.5%	1.68	1.45	1.63	1.9	1.48
MCV	Mean	fL	>85	82.86	84.12	87.39	80.4	95.08
	CV%	%	<2.5%	1.28	0.89	1.75	1.1	0.71
RDW CV	Mean	%	> 12.0	13.31	13.08	13.51	13.08	12.62
	CV%	%	< 5%	4.39	2.85	3.21	3.78	3.02
RDW SD	Mean	fL	> 25	41.04	42.21	39.05	40.75	41.23
	CV%	%	< 5%	1.09	1.27	1.79	1.69	1.51
PLT	Mean	103/μL	> 200	295.42	353.28	319.14	251.35	215.38
	CV%	%	< 10%	6.95	4.57	3.04	3.96	3.35
MPV	Mean	fL	> 7.0	9.44	8.89	8.52	9.58	9.72
	CV%	%	< 5%	1.7	1.45	2.54	1.4	1.64
LYMPH %	Mean	%	> 15	30.78	34.68	46.46	40.79	38.15
	CV%	%	< 5%	4.13	2.5	4.99	2.47	2.68
MID %	Mean	%	> 5	5.98	5.84	5.61	5.91	6.74
	CV%	%	< 10%	5.89	5.69	7.19	6.19	7.27
GRAN %	Mean	%	> 50	63.24	59.48	47.91	53.3	55.12
	CV%	%	< 5%	2.37	1.59	4.84	1.76	1.81

Within run Imprecision (Using clinical samples of the specified range)

Table 4:

Parameters	Value	Unit	Range CV % Specification	Normal control (Lot#)	Low control (Lot#)	High control (Lot#)
WBC	Mean	103/μL	> 6.0	6.98	2.26	15
	CV%	%	< 4%	2.7	4.8	2.5
RBC	Mean	106/μL	> 4.0	4.34	2.23	5.4
	CV%	%	< 4%	3.7	3.5	1.8
HGB	Mean	g/dL	> 12.0	11.91	6	16.2
	CV%	%	< 2.5%	2.2	2.3	1.7
HCT	Mean	%	> 35.0	33.12	14.88	42
	CV%	%	< 5%	4.3	2.7	4.9
MCV	Mean	fL	>85	77.11	66.66	77.8
	CV%	%	<5%	2.4	2.3	4.8
RDW CV	Mean	%	> 12.0	17.11	18.21	17
	CV%	%	< 7%	4.2	5.4	6.1
RDW SD	Mean	fL	> 25	49.14	47.98	50.9
	CV%	%	< 7%	6.3	6.5	5.8
PLT	Mean	103/μL	> 200	264.86	97.34	554
	CV%	%	< 10%	3.8	7.7	7.9
MPV	Mean	fL	> 7.0	12.15	11.22	12.8
	CV%	%	< 5%	3.6	2.7	4.4
LYMPH %	Mean	%	> 15	34.15	48.9	19.2
	CV%	%	< 5%	3.3	3.8	4.8
MID %	Mean	%	> 5	7.2	7.91	7
	CV%	%	< 10%	8.9	8.8	9.7
GRAN %	Mean	%	> 50	59.32	43.18	73.9
	CV%	%	< 5%	2.4	3.4	4.8

Long term Imprecision (Using tri-level control)

Table 5: Correlation of Mispa Count X with comparator analyzers (Beckman Coulter DxH 800 & Sysmex XN 1000)

Parameters	Measured range	Comparison with Beckman Coulter DxH 800			Comparison with Sysmex XN 1000			
		r2 Value	Computed equation	Bias	r2-Value	Computed equation	Bias	Manufacturer Specification
WBC (103/μL)	2.5 - 28	0.9765	y = 0.9499x + 0.7787	± 0.233	0.9726	y = 0.9478x + 1.136	± 0.72	>0.95
RBC (106/μL)	2.25 - 9.0	0.991	y = 1.0276x - 0.1336	± 0.014	0.9514	y = 0.9737x + 0.1534	± 0.038	>0.95
Hb (g/dL)	6.5 - 20	0.9875	y = 0.9873x + 0.1399	± 0.012	0.9579	y = 0.9515x + 0.5684	± 0.027	>0.95
MCV (fL)	60 - 110	0.9593	y = 0.9498x + 4.3585	± 0.129	0.9450	y = 0.9556x + 3.8101	± 0.059	>0.9
Plt (103/μL)	25 - 750	0.9708	y = 1.0143x - 7.7128	± 4.36	0.9550	y = 1.007x - 2.9527	± 1.22	>0.95
MPV	6 - 12	0.8848	y = 0.798x + 1.5664	± 0.0341	0.8330	y = 1.2643x - 1.7127	± 0.258	≥ 0.90
RDW-CV	12 - 30	0.7985	y = 1.011x + 0.0094	± 0.425	0.8234	y = 0.8322x + 2.3449	± 0.0036	≥ 0.75
RDW-SD	35 - 80	0.7533	y = 1.0346x - 1.295	± 0.1625	0.8159	y = 0.9152x + 4.0698	± 0.078	≥ 0.75
Lymph # (103/μL)	0.3 - 7.5	0.926	y = 1.0802x + 0.1256	± 0.300	0.961	y = 1.0016x + 0.2664	± 0.270	≥ 0.90
Mid # (103/μL)	0.1 - 2.0	0.9082	y = 0.9402x + 0.0027	± 0.048	0.8729	y = 0.8132x + 0.0814	± 0.0047	≥ 0.9
Gran # (103/μL)	0.4 - 22	0.9531	y = 0.9658x + 0.56	± 0.376	0.9672	y = 0.9883x + 0.4848	± 0.4273	≥ 0.90

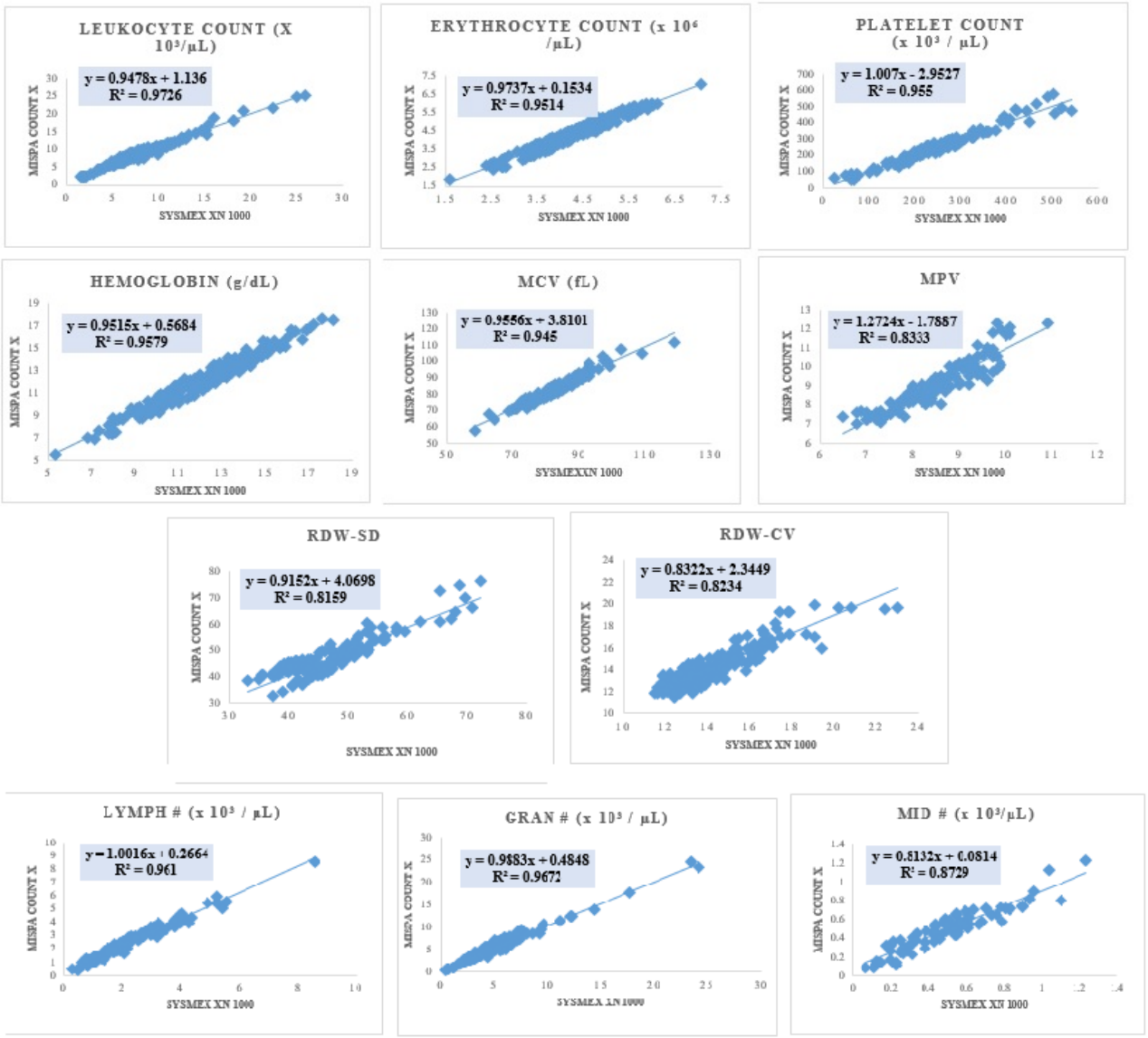

Fig. 2: Comparison of hematology parameters of Mispa Count X (Agappe Diagnositcs) with Sysmex XN 1000 (Sysmex Corporation)

2.7. Sample stability

Blood samples collected from 5 healthy volunteers were used for this study. The sample stability was tested at 1^{st}, 4^{th}, 8^{th} and 24^{th} hour after blood collection. The samples are stored at room temperature (24 – 30 °C) and low temperature (4 – 8 °C). The deviation of the test results of the various aged samples and temperatures were calculated and compared.[19]

2.8. Calibration and quality control

The calibration of the test analyzer was performed by running the calibrator 10 times and the average is taken. It has been calibrated against the assigned values of the calibrator. The quality control was performed throughout the study period to ensure the performance stability of the calibration.

3. Results

Mispa Count X exhibited an average background of 0.1 ($10^3/\mu$L), 0.02 ($10^6/\mu$L) and 4 ($10^3/\mu$L) for total WBC, RBC and platelets respectively. The equipment showed a good linearity range of 0.5 to 120, 0.25 to 7.0, 1.2 – 20 and 20 to 2000 for WBC ($10^3/\mu$L), RBC ($10^6/\mu$L), hemoglobin (mg/dL) and PLT ($10^3/\mu$L) respectively (Table 1). Mispa count X exhibited a negligible carry-over of <1.5% for WBC, RBC and platelets counts as well as haemoglobin measurement from previously run high sample and blank

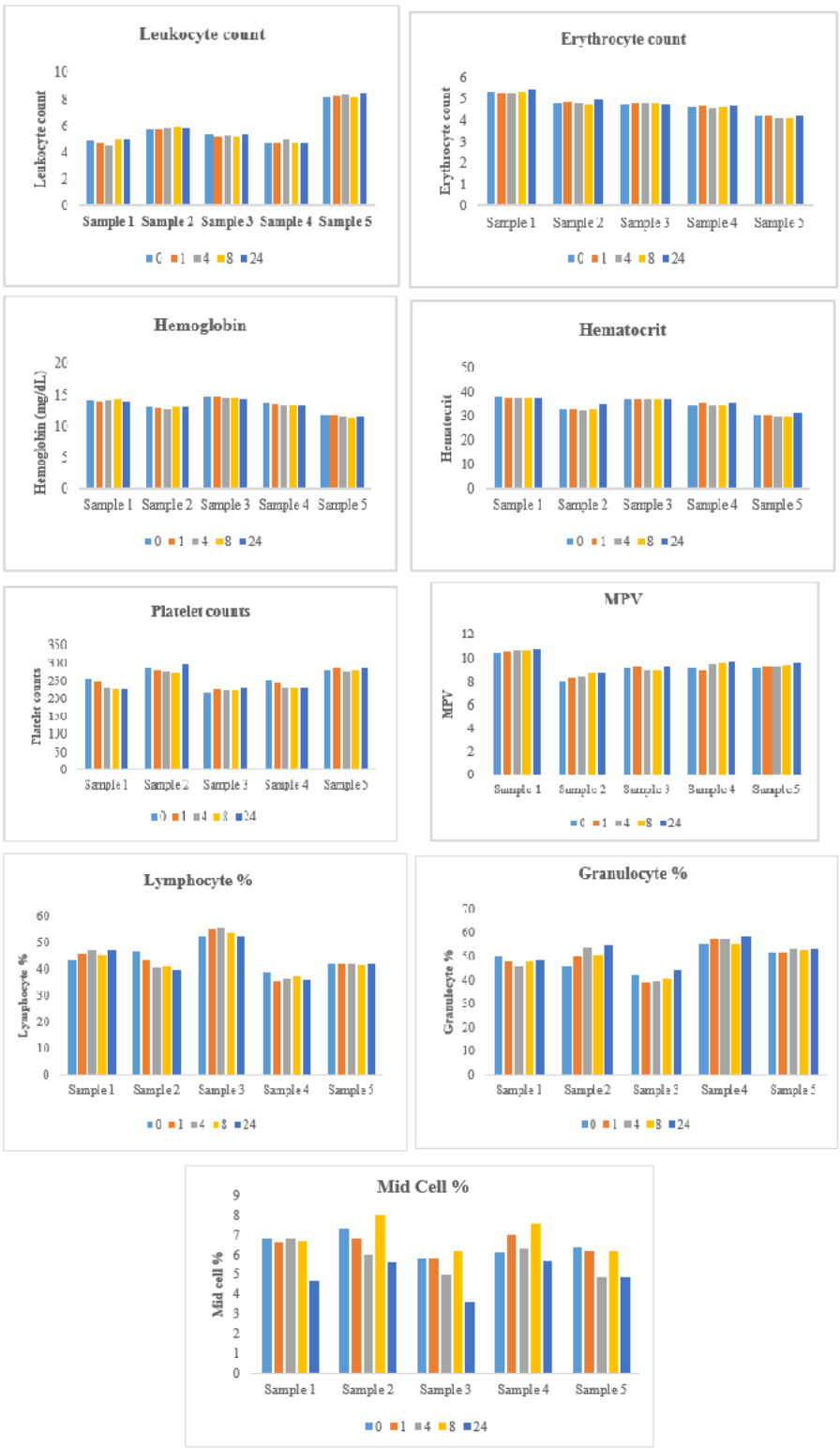

Fig. 3: Sample stability. Normal blood samples incubated at room temperature and tested at 0^{th}, 1^{st}, 2^{nd}, 4^{th}, 8^{th}, 24^{th} and 48^{th} hour.

run (Table 2). The CV% for both intra-run precision (a) and inter-run precision (b) of Mispa Count X were < 10% for all parameters which meets the equipment specifications (Table 3). Mispa Count X produced an acceptable r^2 values (> 0.90) on comparison with Sysmex XN-1000 and Beckman Coulter DxH800 except for mid cell counts and MPV measurements which was 0.9082 and 0.8729 for mid cell counts and 0.8834 and 0.8330 for MPV. The results of comparability and bias estimation are illustrated in Table 5 and Figures 1 and 2. The sample stability shows no significant deviation within 24 hrs of storage at room temperature for any parameters except for Mid%. The average CV% shown were 2.52%, 1.16%, 1.30%, 1.45%, 3.31%, 2.49%, 3.48%, 3.77% and 14.62% respectively for WBC, RBC, Hb, HCT, PLT, MPV, Lym%, Gran% and Mid% (Figure 3).

4. Discussion

Mispa Count X is the first completely indigenous Hematology analyzer which works on the principle of impedance technology. The technical validation of this newly developed analyzer is performed by following CLSI guidelines and proven for commercialization.

The overall performance of Mispa Count X was satisfying. It delivers the results of all parameters with accuracy and precision. The analyzer exhibited no significant carry over from a previous high specimen run and blank run. The CV% obtained were within the claimed limit (<1.5%) and thus is acceptable according to EP5-A2.[17] The linearity range of Mispa Count X (0.5 – 120 x $10^3/\mu$L for WBC, 0.25 – 7.0 x $10^6/\mu$L for RBC, 1.2 – 20 mg/dL for Hb and 20 - 2000 x $10^3/\mu$L for platelet) are appropriate for a 3-part hematology analyzer.[14] The analyzer has a good performance correlation with Beckman Coulter DxH800 and Sysmex XN1000 for all parameters except for mid cell count and MPV which produced a lower r^2 value < 0.90. The comparator analyzers were much advanced versions than Mispa Count X which could produce more reliable differential counts. Considering the fact that the 3-part analyzer aids only the primary screening of samples and the golden standard of microscopic examination of smear is recommended for any abnormality confirmation, the deviation from specification in monocyte count is acceptable.[18] Similar monocyte measurement variation is already been reported.[13] Mispa Count X produces flags for all high and low measurements of each parameters which ease the task of the technician by limiting the number of samples for microscopic examination.

According to Imeri, the technology of the analyzer and its performance capability affects the sample stability.[19] Mispa Count X produced stable results for 24 hours at room temperature. The analyzer functions with a cyanide free and azide free reagent system which causes no harm to the environment.

The wide linearity ranges, negligible carry over, good precision CV% and acceptable bias and r^2 values on comparison with both Coulter DxH800 and Sysmex XN1000 proved that the newly developed analyzer could produce reliable and comparable results and it performs equally well as any other already proven equipment.

5. Conclusion

Mispa Count X opens up the possibility of replacement of the imported, expensive analyzer with a new, Indian made, relatively less expensive analyser with high level of performance, affordable for the rural population.

6. Declaration

This manuscript has not been published elsewhere and is not under consideration by another journal.

7. Conflicts of Interest

Authors declare no conflict of interest.

8. Informed Consent

Whole blood samples were collected after informed consent and used for this study. No patient details and medical history were used for the manuscript.

9. Ethics Approval

The institutional ethical committee approval has been taken before conducting the evaluation and the whole study was conducted following the guidelines.

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